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PTO/SB/21 (05-03)

Approved for use through 04/30/2003. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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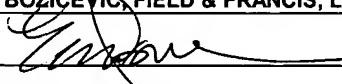
(to be used for all correspondence after initial filing)

Application Number	10/055,794	Certificate
Filing Date	January 17, 2002	
Issued Patent No.	6,977,165	FEB 10 2006
Issued Date	December 20, 2005	
First Named Inventor	FARMER, ANDREW ALAN	of Correction
Group Art Unit	1636	
Examiner Name	MARVICH, MARIA B.	
Total Number of Pages in This Submission	26	Attorney Docket Number

### ENCLOSURES (check all that apply)

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<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
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<input type="checkbox"/> After Final	<input type="checkbox"/> Petition	<input checked="" type="checkbox"/> Petition for Certificate of Correction & Certificate of Correction (Total 3 pages.)
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<input type="checkbox"/> Express Abandonment Request	Change of Correspondence Address	<b>Copy of the Amendment and Response filed on February 17, 2005</b>
<input type="checkbox"/> Information Disclosure Statement	<input type="checkbox"/> Terminal Disclaimer	<b>Notice of Allowance with Examiner's amendment dated May 6, 2005</b>
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	<b>Remarks</b>	

### SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Signing Attorney/Agent (Reg. No.)	EDWARD J. BABA, 52,581 BOZICEVIC, FIELD & FRANCIS, LLP
Signature	
Date	February 6, 2006

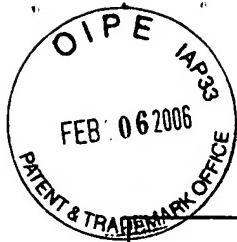
FEB 13 2006

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This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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<p><b>PETITION FOR CERTIFICATE OF CORRECTION UNDER 37 C.F.R. § 1.322 FOR PATENT AND TRADEMARK OFFICE ERROR</b></p> <p>Mail Stop DAC Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450</p>	Attorney Docket No.	CLON-069/P-146
	First Named Inventor	Andrew Alan Farmer
	Application Number	10/055,794
	Filing Date	January 17, 2002
	Patent Number	6,977,165
	Issue Date	December 20, 2005
	Title	SEQUENCE SPECIFIC RECOMBINASE-BASED METHODS FOR PRODUCING INTRON CONTAINING VECTORS AND COMPOSITIONS FOR USE IN PRACTICING THE SAME

Sir:

Applicants petition under 37 C.F.R. § 1.322 for a Certificate of Correction to correct errors in the claims for the above-identified patent due to Patent and Trademark Office error.

Transmitted herewith for filing is a Certificate of Correction for the above-identified patent. Please make the following correction to Claim 9.

In Claim 9, column 66, line 57, please replace the words "has been inserted" with the words -- further comprises a host cell --.

Enclosed is a copy of the Amendment and Response filed on February 17, 2005, and the Notice of Allowance with Examiner's amendment dated May 6, 2005, which show the correct form of the Claim. Also enclosed, is a copy of the relevant page of the issued patent showing the incorrect language of the claims that resulted from Patent and Trademark Office error.

FEB 13 2006

USSN: 10/055,794  
Atty Dkt: CLON-069

It is believed that no fee is due since the error was made by the Patent and Trademark Office. However, the Commissioner is hereby authorized to charge any fees under 37 C.F.R. § 1.20 which may be required by this paper, or to credit any overpayment, to Deposit Account No. 50-0815.

Respectfully submitted,  
BOZICEVIC, FIELD & FRANCIS LLP

Date: Feb. 13, 2006

By:



Edward J. Baba  
Registration No. 52,581

BOZICEVIC, FIELD & FRANCIS LLP  
1900 University Avenue, Suite 200  
East Palo Alto, CA 94303  
Telephone: (650) 327-3400  
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FEB 13 2006

**UNITED STATES PATENT AND TRADEMARK OFFICE**  
**CERTIFICATE OF CORRECTION**

PATENT NO. : 6,977,165  
DATED : Dec. 20, 2005  
INVENTOR(S) : Andrew Alan Farmer

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

In Claim 9, column 66, line 57, please replace the words "has been inserted" with the words -- further comprises a host cell --.

MAILING ADDRESS OF SENDER:

BOZICEVIC, FIELD & FRANCIS LLP  
1900 University Avenue, Suite 200  
East Palo Alto, CA 94303

PATENT NO: 6,977,165

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FEB 13 2006

-continued

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What is claimed is:

1. A composition for use in preparing an intron containing vector, said composition comprising:

a donor vector comprising at least one splice site and an acceptor vector comprising at least one splice site, wherein said donor and acceptor vectors each comprise at least one sequence-specific recombinase target site and wherein one of said donor and acceptor vectors comprises two sequence-specific recombinase target sites and the other of said donor and acceptor vectors comprises a single sequence-specific recombinase target site, wherein all of said sequence-specific recombinase target sites are able to recombine with each other.

2. The composition according to claim 1, wherein said donor vector comprises two sequence-specific recombinase target sites and said acceptor vector comprises a single sequence-specific recombinase target site.

3. The composition according to claim 2, wherein said two sequence-specific recombinase target sites on said donor vector are oriented in the same direction.

4. The composition according to claim 1, wherein said donor vector comprises a single sequence-specific recombinase target site and said acceptor comprises two sequence-specific recombinase target sites.

5. The composition according to claim 4, wherein said two sequence-specific recombinase target sites of said acceptor vector are oriented in the same direction.

6. The composition according to claim 1, wherein said system further comprises a sequence specific recombinase.

7. The composition according to claim 1, wherein said sequence-specific recombinase target sites are selected from the group consisting of: lox sites, att sites, dif sites and frt sites.

8. The composition according to claim 1, wherein said donor and acceptor vectors are plasmids, cosmids, bacis, yacs or viruses.

9. The composition according to claim 1 wherein said composition [has been inserted].

10. The composition according to claim 1, wherein said at least one splice site in each of said donor and acceptor vectors comprises a splice donor and a splice acceptor sequence.

11. A kit for use in producing an expression vector, said kit comprises:

(a) a donor vector comprising a splice site; and  
 (b) an acceptor vector comprising a splice site;  
 wherein each of said donor and acceptor vectors further comprises at least one sequence-specific recombinase

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## TRANSMITTAL FORM

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<p style="text-align: center;"><b>TRANSMITTAL FORM</b></p> <p>(to be used for all correspondence after initial filing)</p>	Application Number: 10/055,794 Filing Date: January 17, 2002 First Named Inventor: FARMER, ANDREW ALAN Group Art Unit: 1631 Examiner Name: Nata Mavrich
Total Number of Pages in This Submission: 10	Attorney Docket Number: CLON-089

**ENCLOSURES** (check all that apply)

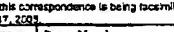
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**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT**

Firm or Individual Name:  <b>BRET E. FIELD, Reg. No. 37,820</b>	
Signature: _____ Date: February 17, 2006	

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Typed or printed name: <b>Donna Mavrich</b> Signature: 	Date: February 17, 2006
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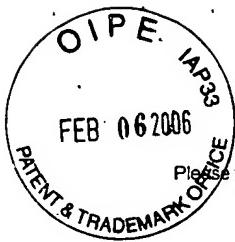
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## TRANSMITTAL FORM

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		Application Number	10/055,794
		Filing Date	January 17, 2002
		First Named Inventor	FARMER, ANDREW ALAN
		Group Art Unit	1636
		Examiner Name	Maria Marvich
Total Number of Pages in This Submission	10	Attorney Docket Number	CLON-069

### ENCLOSURES (check all that apply)

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| <input type="checkbox"/> Affidavits/declaration(s)                           | <input type="checkbox"/> Petition to Convert to a Provisional Application | <input type="checkbox"/> Status Letter   |
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Remarks

### SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual Name	BRET E. FIELD, Reg. No. 37,620
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Date	February 17, 2005

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Typed or printed name	Donna Macedo
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Date	February 17, 2005

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VIA FACSIMILE  
703-872-9306

<b>AMENDMENT AND RESPONSE UNDER 37 C.F.R. §1.111</b>  Address to: Assistant Commissioner for Patents Washington, D.C. 20231	Application Number	10/055,794
	Confirmation Number	7438
	Filing Date	January 17, 2002
	First Named Inventor	Andrew Alan Farmer
	Examiner	Maria Marvich
	Group Art	1636
	Attorney Docket No.	CLON-069/ P-146

Sir:

This amendment is responsive to the Office Action dated November 30, 2004 for which a three-month period for response was given making this response due on or before February 28, 2005. Accordingly, this response is timely filed.

In view of the amendments to the claims and the remarks put forth below, reconsideration and allowance are respectfully requested.

FEB 13 2006

## AMENDMENTS

### In the Specification:

Please replace the paragraph on page 54, lines 31-37 with the following rewritten paragraph.

Sequence for (HN)6 tag within Splice donor oligo:

Top : GGT CAT AAT CAT AAT CAT AAT CAC AAC TAG  
Bottom: CCA GTA TTA GTA TTA GTA TTA GTA TTA GTG TTG ATC  
Peptide encoded: Gly His Asn His Asn His Asn His Asn His Asn stop

(SEQ ID NOS:13, 14, 17 14 17 15)

**In the Claims:**

Please enter the following amendments.

1. **(Canceled)**
2. **(Currently Amended)** A sequence-specific recombinase based system for use in preparing an intron containing vector, said system comprising:  
a donor vector comprising at least one splice site and an acceptor vector comprising at least one splice site, wherein said donor and acceptor vectors each comprise at least one sequence-specific recombinase target recognition site and wherein one of said donor and acceptor vectors comprises two sequence-specific recombinase target recognition sites and the other of said donor and acceptor vectors comprises a single sequence-specific recombinase target recognition site, wherein all of said sequence-specific recombinase sequence-specific sites are able to recombine with each other.
3. **(Currently Amended)** The system according to Claim 2, wherein said donor vector comprises two sequence-specific recombinase target recognition sites and said acceptor vector comprises a single sequence-specific recombinase target recognition site.
4. **(Currently Amended)** The system according to Claim 3, wherein said two sequence-specific recombinase target recognition sites on said donor vector are oriented in the same direction.
5. **(Currently Amended)** The system according to Claim 2, wherein said donor vector comprises a single sequence-specific recombinase target recognition site and said acceptor comprises two sequence-specific recombinase target recognition sites.

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6. **(Currently Amended)** The system according to Claim 5, wherein said two sequence-specific recombinase target recognition sites of said acceptor vector are oriented in the same direction.

7. **(Previously Presented)** The system according to Claim 2, wherein said system further comprises a sequence specific recombinase.

8. **(Currently Amended)** The system according to Claim 2, wherein said sequence-specific recombinase target recognition sites are selected from the group consisting of: lox sites, att sites, dif sites and frt sites.

9. **(Previously Presented)** The system according to Claim 2, wherein said donor and acceptor vectors are plasmids, cosmids, bac<sub>s</sub>, yacs or viruses.

10. **(Previously Presented)** The system according to Claim 2, wherein said system further comprises a host cell.

11. **(Previously Presented)** The system according to Claim 2, wherein each of said donor and acceptor vectors comprise a splice donor and a splice acceptor sequence.

12.-20. **(Canceled)**

21. **(Currently Amended)** A kit for use in producing an expression vector, said kit comprising:

at least one of:

- (a) a donor vector comprising a splice site; and
- (b) an acceptor vector comprising a splice site;

wherein each of said donor and acceptor vectors further comprises at least one sequence-specific recombinase target recognition site and wherein one of said donor

and acceptor vectors comprises two sequence-specific recombinase target recognition sites and the other of said donor and acceptor vectors comprises a single sequence-specific recombinase target recognition site, wherein all of said sequence-specific recombinase target recognition sites are able to recombine with each other.

22. (Original) The kit according to Claim 21, wherein said kit comprises both said donor and acceptor vectors.

23. (Currently Amended) The kit according to Claim 21, wherein said kit further comprises a sequence specific recombinase that recognizes said sequence-specific recombinase target recognition sites.

24. (Currently Amended) A method of producing an intron containing vector, said method comprising:

combining a splice sequence comprising donor vector and a splice sequence comprising acceptor vector, wherein one of said donor and acceptor vectors comprises two sequence-specific recombinase target recognition sites and the other of said donor and acceptor vectors comprises a single sequence-specific recombinase target recognition site, wherein all of said sequence-specific recombinase target recognition sites are able to recombine with each other, with a recombinase under conditions sufficient for site-specific recombination to occur to produce said intron containing vector.

25. (Currently Amended) The method according to Claim 24, wherein said donor vector comprises two sequence-specific recombinase target recognition sites and said acceptor vector comprises a single sequence-specific recombinase target recognition site.

26. (Currently Amended) The method according to Claim 24, wherein said donor vector comprises a single sequence-specific recombinase target recognition site and

said acceptor vector comprises two sequence-specific recombinase target recognition sites.

27. **(Original)** The method according to Claim 24, wherein said sequence specific recombinase is selected from the group consisting of: recombinases, transposases and integrases.

28. **(Original)** The method according to Claim 24, wherein said sequence specific recombinase is Cre recombinase.

29. **(Currently Amended)** The method according to Claim 24, wherein said sequence-specific recombinase target recognition sites are selected from the group consisting of: lox sites, att sites, dif sites and frt sites.

30. **(Original)** The method according to Claim 29, wherein said recombinase recognition sites are lox sites.

31.-37. **(Canceled)**

### **REMARKS**

In view of the following remarks, the Examiner is respectfully requested to withdraw the rejections and allow Claims 2-11 and 21-30, the only claims pending and currently under examination in this application.

### **Formal Matters**

Claims 2-11 and 21-30 are pending after entry of the amendments set forth herein.

Claims 2-11 and 21-30 were examined. Claims 2-11 and 21-28 were rejected and claims 29 and 30 were objected to. No claims were allowed.

Claims 2-6, 8, 21, 21, 23-26, and 29 have been amended. Support for the amendments can be found in the claims as originally filed and throughout the specification at, for example: page 4, lines 15-22, and page 42, lines 11-16.

The specification has been amended on page 54 in order to correct a sequence identification reference number.

As the above amendments introduce no new matter to the application, their entry is respectfully requested.

### **Allowable subject matter**

The Applicants express gratitude in the Examiner's indication that claims 29 and 30 are allowable subject matter.

### **Objection to the Specification**

The specification has been objected to for disclosing three sequences and providing four sequence identification numbers. The specification has been amended on page 54 to correct the sequence identification reference numbers. Therefore, this rejection may be withdrawn.

FEB 13 2006

**Rejection under 35 U.S.C. § 112, second paragraph**

***Claims 2-11***

Claims 2-11 have been rejected under 35 U.S.C. §112, second paragraph, for allegedly being indefinite for reciting "a sequence specific recombinase based system." This rejection is respectfully traversed.

In the spirit of expediting prosecution and without conceding as to the correctness of the rejection, Claim 2 has been amended to recite "a system". The Applicants note that the specification on page 42, lines 8-16, specifically describes a "system". In particular, the specification provides that "the subject systems at least include a donor vector and an acceptor vector as described above" (specification, page 42, lines 10-12).

As such, in view of the amendments to the claims, this rejection may be withdrawn.

***Claims 2-7, 9-11, and 21-28***

Claims 2-7, 9-11, and 21-38 have also been rejected under 35 U.S.C. § 112, second paragraph for allegedly being indefinite for reciting "recombinase recognition site." This rejection is respectfully traversed.

In the spirit of expediting prosecution and without conceding as to the correctness of the rejection, the claims have been amended for clarity to recite "sequence-specific recombinase target site". The Applicants note that the specification on page 4, lines 16-22 specifically describes a "sequence-specific recombinase target site". In particular, the specification provides that a sequence-specific recombinase target sites "are recognized by a sequence- or site-specific recombinase and which become the crossover regions during a site-specific recombination event" (specification, page 4, lines 19-20).

As such, in view of the amendments to the claims, this rejection may be withdrawn.

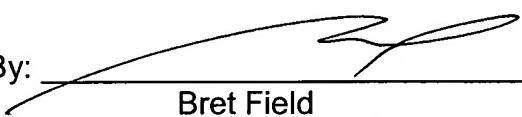
**Conclusion**

The Applicants respectfully submit that all of the claims are in condition for allowance, which action is requested. The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, Order Number CLON-069.

Respectfully submitted,  
BOZICEVIC, FIELD & FRANCIS LLP

Date: February 17, 2005

By:

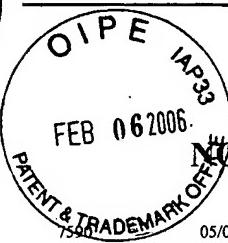
  
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Registration No. 37,620

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**NOTICE OF ALLOWANCE AND FEE(S) DUE**

BOZICEVIC, FIELD & FRANCIS (BD BIOSCIENCES)  
1900 UNIVERSITY AVENUE  
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EAST PALO ALTO, CA 94303

**RECEIVED**

MAY 10 2005

EXAMINER

MARVICH, MARIA

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 05/06/2005

Bozicevic, Field, & Francis

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/055,794	01/17/2002	Andrew Alan Farmer	CLON-069	7438

TITLE OF INVENTION: SEQUENCE SPECIFIC RECOMBINASE-BASED METHODS FOR PRODUCING INTRON CONTAINING VECTORS AND COMPOSITIONS FOR USE IN PRACTICING THE SAME

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1400	\$300	\$1700	08/08/2005

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

**HOW TO REPLY TO THIS NOTICE:**

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B - Fee(s) Transmittal should be completed and returned. If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

**IMPORTANT REMINDER:** Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/055,794	01/17/2002	Andrew Alan Farmer	CLON-069	7438
041064	7590	05/06/2005	EXAMINER	
BOZICEVIC, FIELD & FRANCIS (BD BIOSCIENCES) 1900 UNIVERSITY AVENUE SUITE 200 EAST PALO ALTO, CA 94303				MARVICH, MARIA
ART UNIT		PAPER NUMBER		
				1636
DATE MAILED: 05/06/2005				

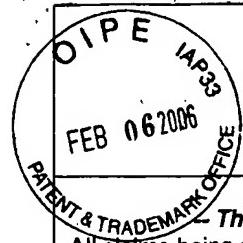
## Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571) 272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.



## Notice of Allowability

Application No.	Applicant(s)
10/055,794	FARMER, ANDREW ALAN
Examiner	Art Unit
Maria B. Marvich, PhD	1636

The MAILING DATE of this communication appears on the cover sheet with the correspondence address--  
 All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included  
 herewith (or previously mailed), a Notice of Allowance (PTO-85) or other appropriate communication will be mailed in due course. THIS  
**NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative  
 of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to an amendment 2/17/05.
2.  The allowed claim(s) is/are 2-11 and 22-30 (now claim 1-19).
3.  The drawings filed on 08 July 2004 are accepted by the Examiner.
4.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All
  - b)  Some\*
  - c)  None
  1.  Certified copies of the priority documents have been received.
  2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6.  CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
  - (a)  including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1)  hereto or 2)  to Paper No./Mail Date \_\_\_\_\_.
  - (b)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

### Attachment(s)

- |   |   |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)           |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                   |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance             |
|   | 9. <input type="checkbox"/> Other _____.  |

### **DETAILED ACTION**

This office action is in response to a response to an amendment filed 2/17/05. Claims 1, 12-20 and 31-37 have been cancelled. Claims 2-6, 8, 21, 23-26 and 29 have been amended. Claims 2-11 and 21-30 are pending in the application.

### **EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Bret Field on 4/29/05.

The application has been amended as follows:

#### **IN THE SPECIFICATION:**

Page 54, line 37 has been amended to read

--(SEQ ID NOS: 13, 14 and 15)--

#### **IN THE CLAIMS:**

In claim 2, line 1, the word "system" prior to the phrase "for use in preparing" has been deleted and the word --composition-- has been inserted.

In claim 2, line 2, the word "system" prior to the phrase "comprising: a donor" has been deleted and the word --composition-- has been inserted.

In claim 2, line 9, the phrase "sequence-specific" prior to the phrase "sites are able" has been deleted and the word --target-- has been inserted.

In claim 3, line 1, the phrase "system according to Claim 2" prior to the phrase "wherein said donor" has been deleted and the phrase --composition according to claim 2-- has been inserted.

In claim 4, line 1, the phrase "system according to Claim 3" prior to the phrase "wherein said two" has been deleted and the phrase --composition according to claim 3-- has been inserted.

In claim 5, line 1, the phrase "system according to Claim 2" prior to the phrase "wherein said donor vector" has been deleted and the phrase --composition according to claim 2-- has been inserted.

In claim 6, line 1, the phrase "system according to Claim 5" prior to the phrase "wherein said two" has been deleted and the phrase --composition according to claim 5-- has been inserted.

In claim 7, line 1, the phrase "system according to Claim 2 wherein said system" prior to "further comprises" has been deleted and the phrase --composition according to claim 2 wherein said composition-- has been inserted.

In claim 8, line 1, the phrase "system according to Claim 2" prior to the phrase "wherein said sequence-specific" has been deleted and the phrase --composition according to claim 2-- has been inserted.

In claim 9, line 1, the phrase "system according to Claim 2" prior to the phrase "wherein said donor vector" has been deleted and the phrase --composition according to claim 2-- has been inserted.

In claim 10, line 1, the phrase "system according to Claim 2 wherein said system" prior to "further comprises" has been deleted and the phrase --composition according to claim 2 wherein said composition-- has been inserted.

Claim 11 has been amended as follows: --The system composition according to Claim claim 2, wherein said at least one splice site in each of said donor and acceptor vectors comprises a splice donor and a splice acceptor sequence. --

Claim 21 (canceled).

Claim 22 has been amended as follows:

-- The kit according to Claim 21, A kit for use in producing an expression vector wherein said kit comprises both donor and acceptor vectors

(a) a donor vector comprising a splice site; and

(b) an acceptor vector comprising a splice site;

wherein each of said donor and acceptor vectors further comprises at least one sequence-specific recombinase target site and wherein one of said donor and acceptor vectors comprises two sequence-specific recombinase target sites and the other of said donor and acceptor vectors comprises a single sequence-specific recombinase target site, wherein all of said sequence specific recombinase target sites are able to recombine with each other. --

In claim 23, line 1, the phrase "Claim 21" prior to "wherein said kit" has been deleted and --claim 22-- has been inserted.

In claim 24, line 3, the word "sequence" prior to "comprising donor vector" has been deleted and -- site-- has been inserted.

In claim 24, line 3, the word "sequence" prior to "comprising acceptor vector" has been deleted and -- site-- has been inserted.

In claim 25, line 1, the phrase "Claim 24" prior to "wherein said donor" has been deleted and --claim 24-- has been inserted.

In claim 26, line 1, the phrase "Claim 24" prior to "wherein said sequence" has been deleted and --claim 24-- has been inserted.

In claim 27, line 1, the phrase "Claim 24" prior to "wherein said sequence" has been deleted and --claim 24-- has been inserted.

In claim 28, line 1, the phrase "Claim 24" prior to "wherein said sequence" has been deleted and --claim 24-- has been inserted.

In claim 29, line 1, the phrase "Claim 24" prior to "wherein said sequence" has been deleted and --claim 24-- has been inserted.

In claim 30, line 1, the phrase "Claim 29" prior to "wherein said sequence" has been deleted and --claim 29-- has been inserted.

### *Conclusion*

Claims 2-11 and 22-30 allowed (now claims 1-19)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B. Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (571)-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maria B Marvich, PhD  
Examiner  
Art Unit 1636

April 29, 2005

*Gerry Leffers*  
GERRY LEFFERS  
PRIMARY EXAMINER